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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/809,029	03/16/2001	Martin C. Barnardo	1181-251	5589

6449 7590 07/17/2002

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EXAMINER

COUNTS, GARY W

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 07/17/2002

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/809,029

Applicant(s)

BARNARDO ET AL.

Examiner

Gary W. Counts

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-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 June 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 18, 19 and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16/4/01 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, claims 1-17 and 20 in Paper No. 9 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Specification

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
- (e) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) BRIEF SUMMARY OF THE INVENTION.
- (g) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (h) DETAILED DESCRIPTION OF THE INVENTION.
- (i) CLAIM OR CLAIMS (commencing on a separate sheet).
- (j) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).

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(k) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

2. The disclosure is objected to because of the following informalities: The specification lacks a section entitled: Brief Description of the Drawings.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-17 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite because applicant insinuates that a binding event has occurred, however, there is no recitation of a step in which a binding event has occurred. See also deficiencies found in claim 2.

Claim 1, line 6 the recitation "functionally equivalent variants" is vague and indefinite. There is no definition provided in the specification for this term and it is unclear what applicant intends.

Claim 1, line 7 "the binding" there is insufficient antecedent basis for this limitation.

Claim 4, the recitation "the heavy chain" there is insufficient antecedent basis for this limitation.

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Claim 8, line 36 the recitation "a variant" is vague and indefinite. There is no definition provided in the specification for the term and it is unclear what applicant is trying to encompass.

Claim 17, line 28 the recitation "via" is vague and indefinite. It is unclear what the term encompasses.

Claim 20, the phrase "optionally" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 20, the phrase "preferably" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

6. Claims 1-3, 5, 9-11, 13, 16 and 17 are rejected under 35 U.S.C. 102(a) as being anticipated by Ogg et al (Detection of HLA-Specific IgG using single recombinant HLA alleles," abstract participants of British Transplantation 2nd Annual Congress, 29-31 March 1999.).

Ogg et al disclose the use of recombinant biotinylated HLA molecules bound onto streptavidin microspheres. Ogg et al disclose contacting these HLA molecules

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with a serum sample and detecting the binding of anti HLA to the HLA molecules. Ogg et al disclose the use of FITC conjugated anti-IgG antibody and flow cytometric analysis. Ogg et al also disclose the use of a ELISA plate (abstract).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 4, and 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ogg et al in view of Tan et al (A novel, highly efficient peptide-HLA class I binding assay using unfolded heavy chain molecules, Journal of Immunological Methods 205 (2) (1997) 201-209).

See above for teachings of Ogg et al.

Ogg et al differ from the instant invention in failing to teach the heavy chain is recombinant.

Tan et al disclose recombinant HLA heavy chain molecules, β_2 -microglobulin and a peptide (abstract). Tan et al disclose that the heavy chain is immobilized to a surface (p. 207, col 2, lines 1-2). Tan et al also disclose that an advantage of the use of this heavy chain is the improved economy and efficiency, as unfolded protein material is in principle easily accessible by recombinant technology.

It would have been obvious to one of ordinary skill in the art to incorporate recombinant HLA heavy chain molecules as taught by Tan et al into the method of Ogg

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et al because Tan et al shows that the use of this heavy chain is the improved economy and efficiency, as unfolded protein material is in principle easily accessible by recombinant technology.

9. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ogg et al in view of Pouletty et al (US 5,292,641).

See above for teachings of Ogg et al.

Ogg et al differ from the instant invention in failing to teach the solid support is nitrocellulose.

Pouletty et al disclose HLA antigens which are immobilized to a nitrocellulose support (col 3, lines 22-54). Pouletty et al disclose that this immobilization of the HLA antigen provides a simple rapid and accurate method for the determination of the presence of antibodies to at least one HLA allele (col 2, lines 1-10).

It would have been obvious to one of ordinary skill in the art to incorporate the use of a nitrocellulose support as taught by Pouletty et al into the method of Ogg et al because Pouletty et al shows that this immobilization of the HLA antigen provides a simple rapid and accurate method for the determination of the presence of antibodies to at least one HLA allele.

10. Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ogg et al in view of Baserga et al (US 6,218,363).

See above for teachings of Ogg et al.

Ogg et al differ from the instant invention in failing to disclose the recombinant HLA is synthesized in a prokaryotic expression system.

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Baserga et al also disclose that MHC or HLA Class I molecules can be produced by recombinant DNA techniques. Baserga et al disclose that the recombinant MHC or HLA Class I molecule is produced in the host by expression. The transformed host may be a prokaryotic or eukaryotic cell. (col 14, lines 1-21). These recombinant molecules retain the therapeutic or diagnostic activity of the naturally occurring molecule and provides methods of identifying MHC Class I peptides.

It would have been obvious to one of ordinary skill in the art to synthesize the recombinant HLA as taught by Baserga et al for the method of Ogg et al because Baserga et al shows that these recombinant molecules retain the therapeutic or diagnostic activity of the naturally occurring molecule and provides methods of identifying MHC Class I peptides.

11. Claim 20 rejected under 35 U.S.C. 103(a) as being unpatentable over Ogg et al in view of Pouletty et al as applied to claims 1-3, 5, 9-13, 16 and 17 above, and further in view of Boguslaski et al (US 5,420,016).

See above for teachings of Ogg et al and Pouletty et al.

Ogg et al and Pouletty et al differ from the instant invention in failing to teach packaging the components into a kit.

Boguslaski et al disclose assembling various system components into a test kit. By assembling these components into test kits, it makes it more convenient and facile for the test operator (col 7, lines 8-11).

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to assemble the various components of the modified method of Ogg et al into kits such as taught by Boguslaski et al because Boguslaski shows that test kits make it more convenient and facile for the test operator.

12. Claims 1-3, 9-11, and 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al (US 5,948,627) in view of Baserga et al (US 6,218,363).

Lee et al disclose a method for detection of HLA antibodies. Lee et al disclose adding serum from a patient to microbeads, each microbead presenting HLA antigens. Lee et al disclose incubating the serum and microbeads for sufficient time for anti-HLA antibodies to bind to the HLA antigens. Lee et al also disclose the addition of a labeled ligand capable of specifically binding with anti-HLA antibodies bound to the HLA antigens and detecting the presence of labeled ligand bound to the HLA antigens.

Lee et al fail to teach the use of recombinant MHC or HLA molecules.

Baserga et al disclose modified (mutant) MHC or HLA Class I molecules that are useful as an antigen for the detection of antibodies thereagainst. (col 13, lines 5-12). Baserga et al also disclose that MHC or HLA Class I molecules can be produced by recombinant DNA techniques. Baserga et al disclose that the recombinant MHC or HLA Class I molecule is produced in the host by expression. The transformed host may be a prokaryotic or eukaryotic cell. (col 14, lines 1-21). These modified MHC or HLA molecules allow for an antigen for raising antibodies or for the detection or purification of antibodies.

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It would have been obvious to one of ordinary skill in the art to substitute the recombinant MHC or HLA molecules as taught by Baserga et al for the HLA molecules of Lee et al because Baserga et al disclose that modified MHC or HLA molecules provide for a method to detect antibodies against these molecules.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (703) 305-1444. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-4242 for regular communications and (703)3084242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Gary W. Counts
Examiner
Art Unit 1641
July 5, 2002



LONG V. LE
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07/11/02